

Massachusetts Department of Public Health
State Laboratory Institute
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SOP: QA.004
Version: 2
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Attachment #2 Coversheet for Reviewers SOP / Manufacturer Insert Comparison

Using the attached form, compare the manufacturer's criteria with the criteria in the laboratory's SOP. If all criteria match, circle "match" for the item. If there is a difference, circle "differences". For any difference, write a brief comment or corrective action below that item. If the test is from the LRN or CDC, please use those documents as the reference documents.

The manufacturer package inserts and Laboratory SOPs have been reviewed.

Paul Elvin 4/6/11
Laboratory Supervisor / Date

Comments:

Wendy S. Smith 4/11/11
Laboratory Director / Date

Comments:

Tracy Stelle 4/11/11
Quality Assurance Director or Manager / Date

Comments:

Attachment #1 Comparison Documentation Grid

SOP Title / number: <i>MTD</i>	Reviewed by / date: <i>PE 4/6/11</i>		
Specimen requirements	QC	Linearity or reportable range	
Specimen type <i>(match)</i> differences	Material: <i>(match)</i> differences	Method reportable limits: <i>(match)</i> differences	
Unacceptable spec.: <i>(match)</i> differences			
Testing limitations: coll date to test date	match differences	Acceptance Criteria: <i>(match)</i> differences	Processing specimens above upper reportable limit: match differences
transportation	match differences		
storage prior to testing	match differences		
SOP Title / number: <i>MGT 960</i>	Reviewed by / date: <i>PE 4/6/11</i>		
Specimen requirements	QC	Linearity or reportable range	
Specimen type <i>(match)</i> differences	Material: <i>(match)</i> differences	Method reportable limits: match differences	
Unacceptable spec.: <i>(match)</i> differences			
Testing limitations: coll date to test date	match differences	Acceptance Criteria: <i>(match)</i> differences	Processing specimens above upper reportable limit: match differences
transportation	match differences		
storage prior to testing	match differences		
SOP Title / number: <i>Quant, team 6010</i>	Reviewed by / date: <i>PE 4/6/11</i>		
Specimen requirements	QC	Linearity or reportable range	
Specimen type <i>(match)</i> differences	Material: <i>(match)</i> differences	Method reportable limits: match differences	
Unacceptable spec.: <i>(match)</i> differences			
Testing limitations: coll date to test date	match differences	Acceptance Criteria: <i>(match)</i> differences	Processing specimens above upper reportable limit: match differences
transportation	match differences		
storage prior to testing	match differences		

Attachment #1 Comparison Documentation Grid

SOP Title / number: <i>Back SIRE Testing</i>			Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements			QC
Specimen type <i>(match)</i> differences			Material: <i>(match)</i> differences
Unacceptable spec.: match differences			Acceptance Criteria: <i>(match)</i> differences
Testing limitations: coll date to test date match differences			Method reportable limits: <i>(match)</i> differences
transportation match differences			Processing specimens above upper reportable limit: match differences
storage prior to testing match differences			
SOP Title / number: <i>MGR 960 PZA</i>			Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements			QC
Specimen type <i>(match)</i> differences			Material: <i>(match)</i> differences
Unacceptable spec.: match differences			Acceptance Criteria: <i>(match)</i> differences
Testing limitations: coll date to test date match differences			Method reportable limits: <i>(match)</i> differences
transportation match differences			Processing specimens above upper reportable limit: match differences
storage prior to testing match differences			
SOP Title / number: <i>Acc prople test</i>			Reviewed by / date: <i>PE 4/6/11</i>
Specimen requirements			QC
Specimen type <i>(match)</i> differences			Material: <i>(match)</i> differences
Unacceptable spec.: <i>(match)</i> differences			Acceptance Criteria: <i>(match)</i> differences
Testing limitations: coll date to test date match differences			Method reportable limits: <i>(match)</i> differences
transportation match differences			Processing specimens above upper reportable limit: match differences
storage prior to testing match differences			